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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
SCHWADRON, RONALD B	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 04/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/767,578	TRAKHT, ILYA	
	Examiner	Art Unit	
	Ron Schwadron, Ph.D.	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 2/20/2004.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 29-34 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 29-33 is/are rejected.

7)☒ Claim(s) 34 is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/20/2004 has been entered.

2. Claims 29-34 are under consideration.

3. It is noted that the specification defines "trioma" as a cell line formed from the fusion of three cells wherein a human-murine hybridoma is fused with a human lymphoid cell (see page 23, lines 19-24).

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 29-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oestberg et al. (US Patent 4,634,664) in view of Gustafsson et al. Applicants arguments have been considered and deemed not persuasive.

Oestberg et al. teach xenogeneic hybridoma fusion partners that do not produce antibody and the use of said cells as fusion partners to produce monoclonal antibodies upon fusion with an antibody producing cell (see column 2, last paragraph and column 3). Oestberg et al. teach that the nonantibody producing xenogeneic hybridoma fusion partner can be made by fusing a myeloma cell to a human lymphocyte (see column 2, last paragraph, continued on column 3). Oestberg et al. teach that the myeloma cell used can be a hybrid cell formed from the fusion of two cells(see column 2, last paragraph). Thus, Oestberg et al. teach use of a three cell containing xenogeneic hybridoma fusion partner that does not produce antibody and the use of said cells as fusion partners to produce monoclonal antibodies. Oestberg et al. do not teach that the cell is a trioma as per the definition of the term in the specification (eg. "trioma" as a cell line formed from the fusion of three cells wherein a human-murine hybridoma is fused with a human lymphoid cell). It is noted that the human-murine hybridoma used in the trioma as per defined in the specification could not produce antibody, because such a cell could not be used a fusion partner. Oestberg et al. teach heteromyeloma cell fusion partners (eg. mouse myeloma/human fused cells, see claim 14). Gustafsson et al. disclose that the term heteromyeloma encompasses a mouse myeloma cell fused to a human PBL (see abstract). Said heteromyeloma would be the same as the nonantibody producing human-murine hybridoma used in the trioma as per defined in the specification. It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have produced the claimed method because Oestberg et al. teach the claimed method except for use of a trioma cell line formed from the fusion of three cells wherein a human-murine hybridoma is fused with a human lymphoid cell, Oestberg teach use of three cell nonantibody producing xenogeneic hybridoma fusion partner containing a hybrid myeloma cell and Oestberg et al. and Gustafsson et al. both teach human heteromyeloma cells (mouse human hybrid myeloma cell line). One of ordinary skill in the art would have been motivated to do the aforementioned because Oestberg et al. teach use of hybrid myelomas as the fusion partner with a nonantibody secreting human lymphocyte (see column 2, last paragraph, continued on next page) to form a three cell nonantibody secreting fusion partner and Oestberg et al. and Gustafsson et al. both teach heteromyeloma cell fusion partners (eg. mouse/human fused cells). The antibody producing hybrid cells can be used in vitro or in vivo to produce antibody (see claim 18). The cells are grown in vitro

under conditions in which antibody is produced (see examples). Oestberg et al. teach freeze storage of desired antibody secreting cells (see column 7, penultimate paragraph). The various assay steps recited in claim 30 involve art known steps for immunoassays (see Examples in Oestberg et al. and Gustafsson et al.). The use of a negative control in immunoassays (eg. a sample not containing the antigen as a background control) as a basis of comparison to a positive result is well known in the art (for example see Gustafsson et al., page 28, column 1, Immunoglobulin-ELISA). The condition recited in claim 30 could be any of the art known diseases disclosed in column 4 of Oestberg et al.

Applicant has argued that Oestberg et al. teach use of a heterohybridoma, not a heteromyeloma. However, the specification appears to define said terms as interchangeable. The specification does not specifically define the terms heteromyeloma or heterohybridoma. However, as previously noted, the specification defines "trioma" as a cell line formed from the fusion of three cells wherein a human-murine hybridoma is fused with a human lymphoid cell (see page 23, lines 19-24). The specification also discloses that, "The present invention provides a trioma cell obtained by fusing a heteromyeloma cell which does not produce any antibody with a human lymphoid cell." (page 3, lines 15-17). The only way these two statements can be reconciled is if the two terms (human-murine hybridoma (a.k.a. heterohybridoma) and heteromyeloma) are used interchangeably. **In addition, the Gustafsson et al. reference specifically teaches that a heteromyeloma is formed by fusion of mouse myeloma cells and human PBLs (see abstract).** Regarding applicants comments about the Exhibits from The Dictionary of Cell and Molecular Biology, said exhibits define the terms hybridoma and myeloma. Said terms are not the terms under consideration. Applicant then goes on interpret what they think said terms might mean in the context of heteromyeloma. However, **the Gustafsson et al. reference specifically teaches that a heteromyeloma is formed by fusion of mouse myeloma cells and human PBLs (see abstract).** Furthermore regarding applicants comments about what the term heteromyeloma means, there is no evidence of record to support applicants assertions because applicant is disclosing their own interpretation of the meaning of said term based on the definition of myeloma.

The MPEP section 2145, section I. discloses:

The arguments of counsel cannot take the place of evidence in the record. In re Schulze, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965); In re Geisler, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997) ("An assertion of what seems to follow from common experience is just attorney argument and not the kind of factual evidence that is required to rebut a prima facie case of obviousness.").

Regarding applicants comments about specific examples disclosed in the specification, while said examples may disclose human myeloma/mouse myeloma hybrid cells, the term heteromyeloma is not disclosed in the specification as only encompassing such cells and the prior art clearly indicates that heteromyeloma encompasses mouse myeloma/human PBL hybrid cells.

5. Claim 34 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ron Schwadron, Ph.D. whose telephone number is 571 272-0851. The examiner can normally be reached Monday to Thursday from 7:30am to 6:00pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached at 571 272 0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ron Schwadron, Ph.D.
Primary Examiner
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